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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,981	11/14/2003	Susan B. Roberts	D0004 DIV	5856

23914 7590 04/14/2005

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/713,981

Applicant(s)

ROBERTS ET AL.

Examiner

Christopher J. Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 61-91 and 95-97 is/are pending in the application.
- 4a) Of the above claim(s) 61-91, 95 and 97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 61-91 and 95-97 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.20.04 **31 301 05**
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group VII (claim 96) in the reply filed on 7 February 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 61-91, 95, and 97 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7 February 2005.

### ***Status of Application, Amendments, and/or Claims***

3. The Supplemental Amendment filed 16 March 2005 has been received and entered in full.

### ***Inventorship***

4. In view of the papers filed 17 March 2005, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(b). The inventorship of this application has been changed by the deletion of Roger Hochoon Pak.

5. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### ***Claim Objections***

6. Claim 96 is objected to because of the following informalities: applicant listed mCHAPSO's IUPAC name as "N-[3(dimethylamino)propyl] 3, 7, 12-trihydroxy(3a, 5b, 7a, 12a)cholan-2-amide]" wherein the identical structure in the art is listed as "N-[3(dimethylamino)propyl] 3, 7, 12-trihydroxy(3a, 5b, 7a, 12a)cholan-24-amide]". The Examiner notes an amide group is R-CONH<sub>2</sub> and an amine is R-NH<sub>2</sub> according to IUPAC conventions. Clarification of the structure and IUPAC name of "mCHAPSO" would greatly aid the Examiner and prosecution. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 1647

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,372,888 (8 February 1983) Hjelmeland and Hjelmeland (November 1980) "A nondenaturing zwitterionic detergent for membrane biochemistry: Design and synthesis" Proc. Natl. Sci. USA 77(11): 6368-6370.

8. US '888 teaches N-[3(dimethylamino)propyl] 3, 7, 12-trihydroxy(3a, 5b, 7a, 12a)cholan-2-amide] as an intermediate in the manufacture of CHAPS and CHAPSO (Col. 7; structure search results). US '888 teaches several operative compounds all of which are zwitterionic derivatives of cholic acid (structure in Col. 5), the most abundant bile acid in human bile (Col. 2 lines 1-10). US '888 also teaches method of using cholic acid and the zwitterionic derivatives of cholic acid as useful in isolating membrane proteins (Col. 3-4). US '888 teaches synthesis of these zwitterionic derivatives of cholic acid by the combination of cholic acid (Col. 5) with a polyethyleneamine such as the one exemplified therein (Col. 6 line 15 Example (1)). The Examiner further notes that the structure of "mCHAPSO" is contemplated by US '888 as it is displayed as a "positive hit" in the structure search of the compound along with the abstract of US '888, therefore being, in essence, "taught".

Art Unit: 1647

9. Hjelmeland teaches that bile salts are a reagent of choice for purifying membrane proteins (integral membrane proteins) because of their ability of preserve an enzymatic activity or other native property (pp. 6368).
10. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make "mCHAPSO" by combining the cholic acid (a bile salt) with the R-(CH<sub>3</sub>)<sub>2</sub>-NH<sub>2</sub> functional group as taught by US '888 and to use it to purify membrane (integral) membrane proteins. The addition of the R-(CH<sub>3</sub>)<sub>2</sub>-NH<sub>2</sub> functional group adds a positive charge making the cholic acid an ionic (cationic) detergent and thus improving it for use in the method of isolating integral membrane proteins.
11. A person of ordinary skill in the art at the time of the invention was made would have been motivated to make mCHAPSO and use it because Hjelmeland teaches that ionic detergents are better than nonionic detergents to isolate integral membrane proteins (pp. 6368).
12. A person of ordinary skill in the art at the time of the invention was made would have a reasonable expectation of success because both cholic acid (the starting material), CHAPSO, CHAPS, and several operative compounds (the products) as taught by US '888 work for this process (Col. 7). Since mCHAPSO is an intermediate between cholic acid and CHAPSO, it shares the key core structures of cholic acid and a polar side group, which bestow upon it detergent properties. A person of ordinary skill in the art at the time of the invention would have a reasonable expectation of its activity because of it belonging to this class of compounds which share the key structures and all share the same function as detergents.
13. Thus the invention as a whole was *prima facie* obvious over the prior art.

*Summary*

14. No claims are allowed.

Art Unit: 1647

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

April 13, 2005

A large, stylized handwritten signature in black ink, likely belonging to Christopher James Nichols, the examiner mentioned in the text. The signature is fluid and cursive, with a large initial 'C' and 'N'.